



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/306,420	05/06/1999	STEPHEN A. LOCARNINI	2551-28	3419

7590

07/10/2002

NIXON & VANDERHYE PC
1100 N GLEBE ROAD 8TH FLOOR
ARLINGTON, VA 22201

EXAMINER

MOSHER, MARY

ART UNIT	PAPER NUMBER
----------	--------------

1648

DATE MAILED: 07/10/2002

24

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory ActionApplication No.
09/306,420Applicant(s)
Locarnini et alExaminer
MosherArt Unit
1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 6/17/02 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid the abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

THE PERIOD FOR REPLY [check only a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 6/17/02. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see NOTE below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE:

3. ☐ Applicant's reply has overcome the following rejection(s):

4. ☒ Newly proposed or amended claim(s) 58 and 65-72 would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See attachment

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: 58 and 65-72

Claim(s) objected to: 78 and 79

Claim(s) rejected: 55-57, 59-64, 74-77

Claim(s) withdrawn from consideration: _____

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other:

Art Unit: 1648

DETAILED ACTION

After entry of the amendment, claims 55-57, 59-64, 74-77 will still be rejected under 102(a) as anticipated by Ling et al. Ling teaches mutant HBV's with substitutions in the B domain, as it is defined in the amended claims. The very same B domain substitutions at amino acids 512 and 526 are recited in applicant's claims 60 and 61. Although Ling does not teach that these B domain mutations result in decreased sensitivity to a nucleoside analog, this sensitivity is a characteristic which necessarily and inherently flows from the mutation itself. Since the claims encompass HBV mutants comprising Phe512Leu or Leu526Met, Ling's disclosure of HBV mutants comprising Phe512Leu or Leu526Met anticipate the claims. The examiner agrees that applicants were the first to recognize the link between mutations in the B domain (495-535) and resistance to nucleotide analogues. However, reciting an unexpected property of an old mutant virus does not make the old virus patentable.

In addition, after entry of the amendment, claims 60 and 61 will be rejected under 112 2nd paragraph as unclear, because parent claim 58 lacks antecedent basis for "said at least one amino acid substitution".

Claim 73 still will be rejected under 112 1st paragraph for new matter, since the DNA polymerase inhibition assay on pages 20-21 and the disclosure of escape variants on pages 2-3 do not reasonably convey the concept of a method for screening the antiviral potential of agents against drug-resistant mutant HBV by measuring lethal doses of agents against said mutants.

Claims 58, 65-72 will be allowable.

Art Unit: 1648


Claims 78 and 79 will be objected to as depending from a rejected claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 10, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800
1600